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10/796,397	03/09/2004	Robert Falotico	CRD-5068	1881

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EXAMINER	
HAGOPIAN, CASEY SHEA	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,397	FALOTICO ET AL.	
	Examiner	Art Unit	
	Casey Hagopian	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 4 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *12-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6-15-2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Information Disclosure Statement filed 6/15/2006.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to a medical device comprising an implantable structure, a basecoat and a topcoat, wherein the basecoat contains rapamycin, a topoisomerase I inhibitor and a first polymer and wherein the topcoat contains a second polymeric material, classified in class 623, subclass 1.46.

II. Claims 12-20 and 23, drawn to a medical device comprising an implantable structure, rapamycin and topoisomerase I inhibitor, classified in class 623, subclass 1.42.

III. Claims 21 and 22, drawn to a method for treating restenosis by administering rapamycin and a topoisomerase I inhibitor, classified in class 604, subclass 500.

IV. Claim 24, drawn to a medical device comprising an implantable structure and a topoisomerase I inhibitor, classified in class 623, subclass 1.42.

The inventions are independent or distinct, each from the other because:

Inventions I, II and IV are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different designs and effects. Group I is the most narrow in scope, claiming a medical device comprising an implantable structure, a basecoat and a topcoat, wherein the basecoat contains rapamycin, a topoisomerase I inhibitor and a first polymer and wherein the topcoat contains a second polymeric material. Group II is drawn to a medical device comprising an implantable structure, rapamycin and topoisomerase I inhibitor and Group IV is drawn to a medical device comprising an implantable structure and a topoisomerase I inhibitor. Groups II and IV do not require any polymer let alone the particular structure of a basecoat and a topcoat that is required in Group I. Group IV further only requires a topoisomerase I inhibitor alone rather than the drug combination of a rapamycin and a topoisomerase I inhibitor required of both Groups I and II. The inventions as claimed are mutually exclusive and there is nothing of record to show them to be obvious variants.

Inventions I, II and IV and Invention III are related as products and a process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case both

scenarios (1) and (2) are possible. Any of the products from groups I, II or IV can be used in the method of Group III. Also, the method does not require a coated implantable medical device, thus the method of Group III may be practiced with another undisclosed/unclaimed materially different product such as direct administration of the drugs via a catheter. In addition, the products may be used to treat other disorders including cancer because topoisomerase I inhibitors are well-known chemotherapy drugs.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required

because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the

restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Carl Evens on 8/14/2007 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-11. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites the limitation "cladribine" in the last line of the claim. Claims 10 and 11 are dependent on claim 9. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims1-3 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borges et al. (US 2005/0033417 A1) in view of Fischell et al. (US 2003/0065382 A1).

Borges teaches coating an implantable medical device with a composition comprising a basecoat and a topcoat, wherein the basecoat includes at least one active agent that is incorporated into a first polymeric material, the basecoat is affixed to the surface of the medical device, and the topcoat contains a second polymeric material which is affixed to the basecoat for the purpose of controlling the elution rate of the at

least one active agent (paragraph 0027). Borges teaches a particular embodiment where the basecoat comprises a fluoropolymer and rapamycin and the topcoat comprises an acrylic polymer (paragraph 0030). Borges also teaches the particular medical devices, stents, anastomosis devices and stent-grafts (abstract; paragraph 0032). Borges further discusses drug combination therapy mainly for the treatment of restenosis and lists possible drugs that may be employed in the invention including rapamycin, cladribine and etoposide (paragraphs 0085-0087).

Borges is silent to the particular drug combination of rapamycin and a topoisomerase I inhibitor.

Fischell teaches a stent that is coated with a composition comprising a polymer and one or more anti-restenosis drugs selected from the group consisting of a finite amount of particular drugs including topoisomerase I inhibitors including adriamycin etoposide, irinotecan and hycamptin (topotecan) as well as rapamycins (abstract; paragraphs 0020 and 0022).

One of ordinary skill in the art would have been motivated to include any combination of the finite number of anti-restenosis drugs suggested by Fischell because they are all art-recognized equivalents used for the same purpose. Both references teach coating an implantable medical device with a composition comprising anti-restenosis drugs, thus one skilled in the art would readily look to Fischell for other anti-restenosis drugs or combinations of anti-restenosis drugs. A practitioner would have reasonably expected a medical device coated with a sustained release coating comprising a combination of anti-restenosis drugs such as a topoisomerase I inhibitor

and a rapamycin. Thus, in Borges, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the particular anti-restenosis drug combination of a rapamycin and a topoisomerase I inhibitor such as iriniotecan or topotecan as suggested by Fischell.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Borges et al. (US 2005/0033417 A1) in view of Fischell et al. (US 2003/0065382 A1) and further in view of Wrenn (USPN 6,485,514 B1).

Borges and Fischell teach the elements discussed above. The references are silent to the particular topoisomerase I inhibitor, camptothecin. Wrenn teaches an implantable medical device coated with a composition comprising camptothecin for the treatment of restenosis (claim 1). One skilled in the art would look to Wrenn because Wrenn teaches that camptothecin is an effective compound for treating restenosis via a coated medical device. It is within the knowledge of one skilled in the art to replace one anti-restenosis drug, or more specifically one topoisomerase I inhibitor, for another because they are art-recognized equivalents used for the same purpose. A practitioner would have reasonably expected a medical device coated with a sustained release coating comprising a combination of anti-restenosis drugs such as the topoisomerase I inhibitor camptothecin and a rapamycin. Thus, in Borges and Fischell, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include camptothecin as suggested by Wrenn.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borges et al. (US 2005/0033417 A1) in view of Fischell et al. (US 2003/0065382 A1) and further in view of Eury et al. (US 2002/0004679 A1). Borges and Fischell teach the elements discussed above. The references are silent to the particular topoisomerase I inhibitors, camptothecin and DX-8951f. Eury teaches an implantable medical device coated with a composition comprising a topoisomerase I inhibitor for the treatment of restenosis (abstract; paragraph 0045). A preferred topoisomerase I inhibitor is camptothecin and analogues thereof including DX-8951f, iriniotecan and topotecan (paragraphs 0035 and 0036). One skilled in the art would look to Eury because Eury teaches that topoisomerase I inhibitors in general, and camptothecin and its analogues in particular, are effective compounds for treating restenosis via a coated medical device. It is within the knowledge of one skilled in the art to replace one anti-restenosis drug, or more specifically one topoisomerase I inhibitor, for another because they are art-recognized equivalents used for the same purpose. A practitioner would have reasonably expected a medical device coated with a sustained release coating comprising a combination of anti-restenosis drugs such as camptothecin or an analogue thereof and a rapamycin. Thus, in Borges and Fischell, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include camptothecin or an analogue thereof as suggested by Eury.

Conclusion

All claims have been rejected; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey Hagopian/

Casey Hagopian
Examiner
Art Unit 1615

CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500